

REMARKS

Before this Amendment, claims 31-45 were pending. By this Amendment, new claim 68 has been added. Therefore, claims 31-45 and 68 are now pending.

Support for new claim 68 is found in the specification, at page 10, lines 20-22.

The abstract

The Office Action stated that the present application does not contain an abstract.

Enclosed herewith, as a separate page, is an abstract. The Applicants request that this abstract, which contains no new matter, be added to the application.

The rejection under 35 U.S.C. §112

Claims 31-45 were rejected as being indefinite. According to the Office Action, the claims are indefinite because they use the word “device” and “device” is not defined in the claims or the specification.

The Applicants respectfully traverse this rejection. The Applicants note that the word “device” appears in the phrase “device for transdermal delivery” and must be considered in that context. That is, it is not the single word “device” that must be assessed for definiteness but rather the phrase “device for transdermal delivery” which must be considered.

The claims are not indefinite at least for the following reasons:

- (1) The phrase “device for transdermal delivery” is clear on its face;
- (2) The phrase “device for transdermal delivery” is well-known in the art; and
- (3) the present specification describes many features of particular embodiments of devices for transdermal delivery.

The phrase “device for transdermal delivery” is clear on its face

This phrase uses no unfamiliar terms or language and would present no special problems of understanding to those skilled in the art. The word “device” cannot present any problems since it is a common word that is being used in its common sense. A “device for transdermal delivery” is simply a device that is used for the transdermal delivery of a pharmaceutical compound.

The phrase “device for transdermal delivery” is well-known in the art

Courts and other tribunals have found that terms that are well-known in the art are not indefinite. See, e.g., *Ex parte Sawyer*, 130 U.S.P.Q. 476 (Pat. Off. Bd. App. 1961), where the Board reversed a rejection for indefiniteness based on the recitation of claim terms that were known in the art. The terms at issue were “cationic agent” and “organic nitrogen base.” The Board found that these terms were not indefinite because the terms were “well known in this art” and therefore “Those skilled in the art would readily understand this terminology.” (130 U.S.P.Q. at 477). See also *Bancorp Services LLC v. Hartford Life Insurance Co.*, 359 F. 3d 1367, 69 U.S.P.Q. 2d 1996 (Fed. Cir. 2004) (a patent claim that uses terms not defined in the patent is

not invalid for indefiniteness if the terms are reasonably discernible because their components have well-recognized meanings).

That the phrase “device for transdermal delivery” is well-known in the art can be seen simply by doing a few simple searches in the databases of the USPTO. The Applicants submit herewith the results of such searches as Exhibits A-D. The searches were as follows:

- the claims of U.S. patents were searched for the exact phrase “device for transdermal delivery.” 27 patents were found to use that exact phrase in their claims alone. See Exhibit A.
- the specifications of U.S. patents were searched for the exact phrase “device for transdermal delivery.” 54 patents were found to have that exact phrase in their specifications. See Exhibit B.
- the claims of U.S. patents were searched for the phrase “transdermal delivery device,” which has the same meaning as the phrase in question. 50 patents were found to use the phrase “transdermal delivery device” in their claims. See Exhibit C.
- the specifications of U.S. patents were searched for the phrase “transdermal delivery device.” 314 patents were found to use this phrase in their specifications. See Exhibit D.

That the phrase in question is so widely used argues that it would be readily understood by those skilled in the art, even absent a specific definition.

The present specification describes many features of particular embodiments of devices for transdermal delivery.

Many portions of the present specification provide details of certain embodiments of the devices for transdermal delivery. For example:

- A particular embodiment of a device for transdermal delivery is depicted in Figure 4 of the present application. The features of this embodiment are described in the specification, at page 10, lines 27-33:

An example for a typical structure of a monolithic transdermal device is reproduced in FIG. 4. The device described there consists of the adhesive matrix, which contains the active ingredient (1), a backing which is inert and impermeable for the ingredients of the adhesive matrix, wherein said backing after the administration of the patch onto the skin of the patient finds itself on the site of the patch which is remote from the skin (2) as well as a layer for protection of the adhesive matrix in storage, detachable immediately before use (3).

- Page 10, lines 20-22, describes certain embodiments where the device is a flat-shaped device for transdermal delivery of the matrix type where the compound of Formula I is present in a polymer layer or polymer paste:

In the case of the inventive device it involves a customary, flat shaped transdermal device/form of medicine of the matrix type, meaning the active ingredient is present either embedded in a polymer layer or polymer paste (dissolved or dispersed).

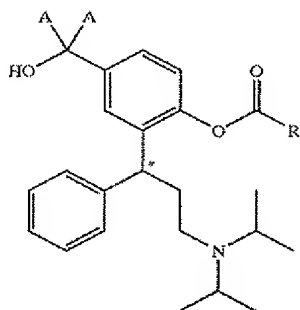
- Page 6, lines 13-15, teaches that the device for transdermal delivery may have a surface area of up to 50 cm² in certain embodiments:

Using such a simply constructed, flat shaped device with a surface of a maximum around 50 cm² it is surprisingly possible, to make the clinically relevant dosing spectrum of the combinations of the general Formula I transdermally available.

- [0040] Page 6, lines 16-26, teaches that the device for transdermal delivery may have a self-adhesive polymer layer:

One object of the invention is therefore a device for the transdermal delivery of a compound of the Formula I

Formula I



wherein A is hydrogen or deuterium, R is C₁₋₆-alkyl, C₃₋₁₀-cycloalkyl or phenyl, which may each be substituted with C₁₋₃-alkoxy, fluorine, chlorine, bromine, iodine, nitro, amino, hydroxyl, oxo, mercapto or deuterium and where the C-atom marked with a star "*" is present in the (R)-configuration, characterized by the fact that the combination of the general Formula I is present in a polymer layer, preferably in a self-adhesive polymer layer (adhesive matrix), dissolved or dispersed and is released through the human skin in a flux rate of 0.5-20 mg per day.

- Page 9, lines 15-26, describes features of the base, the polymer layer, the total weight, and relationships of the weight of components or the device for transdermal delivery:

In an especially preferred form of execution of the invention the device is characterized in that it

- (a) exhibits a base of a maximum 50 cm²,
- (b) incorporates a self-adhesive polymer layer, which
 - (b1) exhibits a weight of 30-300 g/m²,
 - (b2) contains 50-95% by weight of a contact adhesive,
 - (b3) contains a compound of the general Formula I in a concentration of 5-40 percent by weight based on the total weight of the polymer layer and especially preferred,
- (c) the said compound of the general Formula I delivers at least 4µg/cm²/hour with a steady-state flux rate through the human skin over a time period of at least 24 hours.

The many descriptions of particular features of particular embodiments of devices for transdermal delivery in the specification would serve to enrich the

common understanding of those skilled in the art and make it even more likely that the use of this phrase in the claims would be easily understood.

The Applicants also note that new claim 68 and old claims 41, 42, and 44 recite certain structural features of particular embodiments of the device for transdermal delivery and thus this rejection is especially inappropriate with respect to these claims.

In view of the above, it is respectfully requested that this rejection be withdrawn.

The time for responding to the Office Action was set for June 7, 2008. Enclosed herewith is a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this paper. Charge any fees associated with the Petition to Kenyon & Kenyon's Deposit Account No. 11-0600.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon LLP's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

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Respectfully submitted,
BY: /Joseph A. Coppola/
Joseph A. Coppola
Reg. No. 38,413

KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200 (telephone)
(212) 425-5288 (facsimile)